

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:) **Chapter 11**
)
W.R. Grace & Co., et al.,) **Case No. 01-01139 (JKF)**
) **(Jointly Administered)**
)
Debtors.)

**Memorandum in Support of the Claimants' Motion to Exclude
Dr. R.J. Lee's Opinion on Cleavage Fragments**

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TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	THE LEGAL STANDARD	2
III.	DISCUSSION	5
	A. Dr. Lee used a protocol that is unpublished and not peer reviewed	6
	B. The consensus in the scientific community is that Libby amphiboles are fibrous and asbestiform in nature	9
	C. W.R. Grace investigated and concluded that Libby amphiboles are fibrous and asbestiform in nature	11
	D. Dr. Lee's opinion contradicts the findings of his own laboratory	13
	1. Dr. Lee's laboratory found predominantly asbestiform tremolite in ZAI	13
	2. Even using extreme measures, Dr. Lee's laboratory could not produce large numbers of non-asbestiform cleavage fragments from Libby tremolite.....	15
	E. Dr. Lee's "cleavage fragments" do not fit the diameter of cleavage fragments in the published scientific literature	17
	F. Dr. Lee's "cleavage fragments" do not fit the aspect ratio of cleavage fragments in the published scientific literature	18
	G. EPA has rejected Dr. Lee's opinions regarding cleavage fragments from Libby vermiculite	23
	H. The results from Dr. Lee's laboratory are unreliable.....	25
IV.	CONCLUSION.....	27

TABLE OF AUTHORITIES

CASES

1.	<u>Daubert v. Merrell Dow Pharm.</u> , 509 U.S. 579 (1993).....	2
2.	<u>In re Paoli R.R. PCB Litig.</u> 35 F.3d 717 (3 rd Cir. 1994).....	3
3.	<u>Kumho Tire Co. v. Carmichael</u> , 526 U.S. 137 (1999).....	3

STATUTES

1.	<u>Fed. R. Evid. 702</u>	2
----	--------------------------------	---

OTHER AUTHORITIES

1.	<u>Ambient Air – Determination of Asbestos Fibers – Direct Transfer Transmission Electron Microscopy Method</u> , Number 10312, International Standards Organization (1995).....	6
2.	<u>Asbestos Strategies, Lessons Learned About Management and the Use of Asbestos</u> , Global Environment & Technology Foundation (Apr. 21, 2003)	11
3.	<u>Campbell, W. J., et al., Selected Silicate Minerals and Their Asbestiform Varieties</u> , Bureau of Mines Information Circular 8751 (1977)	18
4.	<u>Campbell, W. J., et al., Relationship of Mineral Habit to Size Characteristics for Tremolite Cleavage Fragments and Fibers</u> , Bureau of Mines Report of Investigations 8367 (1979)	20
5.	<u>EPA Summary On-Site Audit Report</u> , R.J. Lee Group, Inc. (May 1, 2001)	25
6.	<u>Lee, R. J., et al., Asbestiform and Nonasbestiform Mineral Growth Habit and Their Relationship to Cancer Studies</u> (Apr. 2003).....	8,9, 19, 23
7.	<u>Lee, R. J., et al., Considerations in the Analysis and Definition of Asbestos Using Electron Microscopy</u> , National Bureau of Standards Special Publication 619 (Mar. 1982)	20
8.	<u>McDonald, J. C., et al., Cohort Study of Mortality of Vermiculite Miners Exposed to Tremolite</u> , British J. of Ind. Med., 43:436-44 (1986)	10

9. McDonald, J. C., et al., Health of Vermiculite Workers Exposed to Trace Amounts of Fibrous Tremolite, British J. of Ind. Med., 45:630-34 (1988) 10
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I. INTRODUCTION

This Science Trial focuses on whether Grace's Zonolite Attic Insulation product (ZAI) contains asbestos fibers that can be released during foreseeable use, thereby contaminating building surfaces and creating a danger to those in the vicinity. ZAI was manufactured from vermiculite mined at Grace's Libby, Montana mine. Libby is a much studied ore body:

- 1) Since the early 1920s, this mine has been the subject of numerous peer-reviewed scientific studies analyzing the amphibole asbestos minerals in the Libby vermiculite deposit.
- 2) In the 1950s, the State of Montana began investigating the incidence of disease among workers at the Libby mine.
- 3) Beginning in the 1960s, Grace studied the asbestos contamination problem associated with the vermiculite at the Libby mine.
- 4) In the 1980s, several medical/scientific investigations were performed regarding the asbestos contamination problem at the Libby mine.
- 5) In the last few years, the Environmental Protection Agency (EPA) has performed extensive investigations into the asbestos contamination problem in the town of Libby and the problems associated with products manufactured with Libby vermiculite.

All these investigations have concluded that Libby vermiculite is contaminated with fibrous amphibole asbestos fibers, and that disturbance of the vermiculite results in the release of airborne asbestos fibers. Yet Grace has put forth Dr. R.J. Lee to dispute this uniform authority.

When Grace was sued by the EPA over the Libby asbestos contamination, it had few options. People were dying. The town was contaminated with asbestos. Some of Grace's usual experts refused to be involved. For instance, Dr. Morton Corn, who has

testified for Grace for two decades, refused to assist it in the Libby litigation.¹ Desperate for some theory to fight liability, Grace approached its perennial microscopy expert, Dr. R. J. Lee. Dr. Lee conjured up a theory that everyone else had been wrong about Libby for decades. It was not really an asbestos problem after all. Rather, Dr. Lee said, the particles measured in Libby were 90% non-asbestos rock slivers called "cleavage fragments" that were harmless.

Dr. Lee's microscopic doubletalk went nowhere in the EPA litigation. The District Court granted summary judgment against Grace on the bulk of the government's claim. Undaunted, Grace has called on Dr. Lee and his cleavage fragment theory again to try to downplay the hazard of ZAI. According to Dr. Lee, 90% of the particles that come from ZAI, which others would measure as asbestos, are not really asbestos even though they have the dimensions of asbestos fibers. Rather, says Dr. Lee, they are harmless cleavage fragments. This testimony is "junk science" that should be excluded.

II. THE LEGAL STANDARD

Federal Rule of Evidence 702 has three requirements for the admission of expert testimony: (1) the witness must be an expert; (2) the witness must testify to scientific, technical, or other specialized knowledge; and (3) the testimony must assist the trier of fact. Dr. Lee intends to provide testimony that contradicts the facts, is unscientific and unreliable, and will mislead rather than assist in determining the truth.

In Daubert v. Merrell Dow Pharmaceuticals, 509 U.S. 579 (1993), the United States Supreme Court held that expert testimony is admissible under Rule 702 if "the reasoning or methodology underlying the testimony is scientifically valid and ... that

¹ Attachment 1, Deposition of Morton Corn at 86:19 – 88:15 (May 29, 2003).

reasoning or methodology properly can be applied to the facts in issue." Id. at 592-93. The Supreme Court set forth a non-exclusive list of four factors to guide the first part of this inquiry, and the Third Circuit has expanded the list to eight:

(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualification of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

In re Paoli R.R. PCB Litig., 35 F.3d 717, 742 n.8 (3rd. Cir. 1994), cert. denied, 513 U.S. 1190 (1995). The inquiry into scientific validity and reliability is intended to be a flexible one, and the enumerated factors "neither necessarily nor exclusively apply to all experts in every case." Kumho Tire Co. v. Carmichael, 526 U.S. 137, 142 (1999). However, "any step that renders the analysis unreliable under the Daubert factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology." In re Paoli, 35 F.3d at 745.

For two decades, Dr. Lee has testified as an expert witness for Grace in its asbestos property damage litigation. In a last ditch effort to minimize the high airborne asbestos concentrations that occur upon ZAI disturbance, Dr. Lee intends to testify that over 90% of what all others have called asbestos fibers are nothing more than harmless cleavage fragments from non-asbestiform amphibole rock.² Dr. Lee has taken two

² As described by Dr. Lee, "When non-asbestiform cleavage minerals such as amphiboles are crushed, fragments are cleaved away from the main crystal mass, a process that produces 'cleavage fragments.' The massive mineral will tend to fracture along sets of systematic planes within the mineral crystal, and some long, thin fragments may result, although the majority of fragments will be short, non-fibrous particles." Attachment 2, Richard J. Lee Report at 11 (April 15, 2003) ("Lee Report").

accepted methodologies for measuring airborne asbestos fibers and modified them to produce an analytical protocol that: (1) has never been published in any peer-reviewed journal; and (2) has not been accepted by the responsible regulatory authorities. Further, Dr. Lee attempts to exclude over 90% of the asbestos fibers counted by Claimants' experts in their ZAI simulation studies by using a mathematical equation that: (1) has never been accepted by any governmental agency for distinguishing between populations of asbestiform fibers and cleavage fragments; and (2) has been rejected by EPA.

Dr. Lee's testimony does not "fit" the facts of this case. As discussed below, the recognized method for distinguishing asbestiform fibers from cleavage fragments is by looking at the overall population of the particles. In contrast, Dr. Lee has excluded particles based on individual analysis using TEM. His methodology has not been peer-reviewed and has been created solely for litigation. The Occupational Safety and Health Administration (OSHA) has indicated that one of the reasons it disapproves of individual particle analysis to distinguish cleavage fragments is because there is an unknown rate of error.³ No standards control the operation of Dr. Lee's technique because Dr. Lee has modified the existing standards to suit Grace's needs. The technique has no relationship to methods which have been established to be reliable, other than the fact that Dr. Lee has modified reliable techniques to the extent that they are now unreliable.

Dr. Lee's opinions are contrary to the peer reviewed consensus in the published scientific literature and are contrary to Grace's own conclusions. Moreover, Dr. Lee's opinions contradict his own testing and observations. His "cleavage fragments" do not fit

³ See Attachment 3, 1992 OSHA Asbestos Standard, § IV - Mineralogical Considerations at 9 (stating that, "when one looks at individual particles (e.g. particles from air sampling filters), sometimes these mineralogical distinctions are not clear. Unfortunately, the data in the record is insufficient at this time to precisely determine how often these situations occur.").

the dimensional criteria for cleavage fragments in the scientific literature. The methodology on which he bases his testimony is directly contradicted by the entire scientific community, including government agencies such as EPA and OSHA. Finally, the reliability of Dr. Lee's laboratory has been questioned by a government investigative audit.

For these reasons, Dr. Lee's opinions concerning cleavage fragments should be excluded.

III. DISCUSSION

In the spring of 2002, Grace commissioned a ZAI simulation study that involved minor disturbance of ZAI at a home in New York. The airborne asbestos concentrations resulting from this minor disturbance, which approached the OSHA Permissible Exposure Limit of 0.1 fibers/cc, would have been significantly higher if Dr. Lee's laboratory had properly counted all asbestos fibers that had been collected. Instead, Dr. Lee's laboratory used its own untested and unpublished protocol to exclude over 90% of the fibers that would have been counted as asbestos fibers by any laboratory that followed accepted scientific protocols.

Claimants' experts also performed a number of ZAI simulation experiments involving various activities, such as vacuuming ZAI with an ordinary shop vac, removing ZAI following a method recommended by Grace, and removing ZAI following a method used by homeowners. They analyzed their samples using a standard analytical technique known as the AHERA method. Without examining any of the Claimants' air sample grids, Dr. Lee opined that over 90% of the asbestos fibers detected in the Claimants' ZAI studies are really cleavage fragments. Dr. Lee bases his opinion on an algorithmic

equation that he acknowledged has not been accepted by any governmental agency for distinguishing between populations of asbestos fibers and cleavage fragments.⁴ In fact, Dr. Lee's use of this equation was rejected by EPA in the Libby Superfund litigation.⁵

As discussed below, Dr. Lee's opinions regarding the amount of cleavage fragments contradict: (1) the scientific consensus that airborne amphiboles from Libby vermiculite are predominantly asbestos in nature; (2) Grace's own findings regarding the fibrous nature of Libby amphiboles; (3) Dr. Lee's own findings from his testing of ZAI; and (4) the consensus of the scientific community on the dimensions of cleavage fragments.

A. Dr. Lee used a protocol that is unpublished and not peer reviewed.

Dr. Lee's laboratory analyzed the Grace simulation studies by both light microscopy (PCM), using the NIOSH 7400 protocol, and by electron microscopy (TEM), using the NIOSH 7402 protocol. However, in an effort to exclude as many asbestos fibers from the test results as possible, "*the TEM procedure was slightly modified to fully identify and enumerate the cleavage fragments (non-asbestos).*"⁶ Dr. Lee also analyzed the air samples using an ISO Standard entitled, Ambient Air – Determination of Asbestos Fibers – Direct Transfer Transmission Electron Microscopy Method.⁷ This standard specifically cautions that it *cannot* be used, as Dr. Lee has used it, to label some particles as "non-asbestos" forms of tremolite:

⁴ Attachment 4, Deposition of Richard J. Lee at 217: 19-22 (June 6, 2003) ("Lee Deposition").

⁵ Id. at 226: 5-16.

⁶ Attachment 2, Lee Report at 34.

⁷ Attachment 5.

This international standard specifies a reference method using Transmission Electron Microscopy for the determination of the concentration of asbestos structures in ambient atmospheres and includes measurements of the lengths, widths, and aspect ratios of the asbestos structures. The method allows determination of the type(s) of asbestos fibers present. *The method cannot discriminate between individual fibers of the asbestos and non-asbestos analogues of the same amphibole mineral.*⁸

The ISO method defines a fiber as “[a]n elongated particle which has parallel or step sides. For the purposes of this international standard, a fiber is defined to have an aspect ratio equal to or greater than 5:1 and a minimum length of 0.5 microns.”⁹ Dr. Lee modified this protocol by using a flow chart he produced at his deposition. This flow chart, entitled Determination of Cleavage/Asbestiforms and dated August 31, 2001, is labeled “Draft – Privileged and Confidential Work Product.”¹⁰ Dr. Lee’s protocol involves the analysis of individual fibers by TEM. In order to eliminate fibers, Dr. Lee has selected criteria which are not supported by scientific data.

To Claimants’ knowledge, Dr. Lee’s protocol has never been published in a peer-reviewed journal, and it has not been accepted by OSHA or EPA. Further, there is no indication of the rate of error in using this protocol. The generally accepted method for distinguishing fibers from cleavage fragments is to view populations of particles as a whole. OSHA has stated, “While one can differentiate between mineral types when populations of particles are examined, when single, isolated particles are examined (e.g.

⁸ Id. at 1.

⁹ Id. at 3.

¹⁰ Attachment 6 at 2-3.

particles from air samples) the ability to differentiate may become more difficult.”¹¹ OSHA concluded:

In summary, the discussion indicates that populations of fibers and populations of cleavage fragments can be distinguished from one another when viewed as a whole. For example, one can look at the distribution of aspect ratios or even widths for a population of particles and can then generally identify that population of particles as being asbestiform or non-asbestiform. However, when one looks at individual particles (e.g. particles from air sampling filters), sometimes these mineralogical distinctions are not clear. Unfortunately the data in the record is insufficient at this time to precisely determine how often these situations occur.¹²

OSHA directs analysts to look for populations of fibers that have the dimensions of asbestos because only the asbestiform habit would produce a population of particles with the appropriate dimensions. “Therefore, we are really analyzing for the habit of amphibole asbestos, not for a particular particle size and shape.”¹³ As discussed below, the population of particles excluded by Dr. Lee as cleavage fragments does not fit the dimensions specified for cleavage fragments in the published scientific literature. Rather, looking at these particles appropriately as a population, they are clearly asbestiform.

Dr. Lee’s recent attempt to analyze individual particles and classify them as asbestiform or non-asbestiform is also contrary to the view he has expressed elsewhere. In April 2003, the National Stone Association published a document co-authored by Dr. Lee entitled The Asbestiform and Nonasbestiform Mineral Growth Habit and Their

¹¹ Attachment 3, 1992 OSHA Asbestos Standard, § IV- Mineralogical Considerations at 7.

¹² Id. at 8.

¹³ Attachment 7, Ann Wylie, Habit of Asbestiform Amphiboles: Implications for the Analysis of Bulk Samples, Advances in Environmental Measurement Methods for Asbestos, ASTM STP 1342 at 60 (M.E. Beard and H.L. Rooks, Eds. 2000).

Relationship to Cancer Studies.¹⁴ This document was prepared "to help people understand who are not in the aggregate industry what the difference between asbestiform and cleavage – rock forming amphiboles are..."¹⁵ The authors state:

Morphological properties are difficult to apply to single particles when classifying them as a cleavage fragment or a fiber. Distinctions on morphology are most reliably made on populations. Furthermore, in air and water samples, in which particles are often less than 5 um in length, the presence of asbestos should be verified in bulk material at the source before identification of particles as asbestos can be reliably made. Bulk materials display the full range of distinctive morphological characteristics, but in fibers collected from air and water, the range of morphological properties is more limited.¹⁶

Elsewhere in the article, Dr. Lee described Libby vermiculite as associated with "Clear Amphibole Asbestos Exposures".¹⁷ Dr. Lee's article casts doubt on the reliability of his current attempt to minimize the asbestos content from Libby vermiculite.

B. The consensus in the scientific community is that Libby amphiboles are fibrous and asbestiform in nature.

In the early 1980s, Dr. J. C. McDonald was hired by Grace to perform an epidemiological study of Grace Libby workers. After evaluating the Libby asbestos and its history, Dr. McDonald concluded:

It is *well established* that the vermiculite deposit in Libby is contaminated by *asbestiform* fibres. Their presence in airborne dust was first mentioned in 1956 in the report of an industrial hygiene survey by the Montana State Board of Health but only recently has further information become available on the nature of Libby fibres.

A systematic study by analytical transmission electron microscopy of airborne fibres collected on membrane filters in various locations of the

¹⁴ Attachment 8.

¹⁵ Attachment 4, Lee Deposition at 8:3-10.

¹⁶ Attachment 8 at 5 (cmphasis added).

¹⁷ Id. at 56.

mine and mill is now in progress. Preliminary findings on samples from the wet mill indicate that fibres exhibit several morphologies. They may be straight with uniform diameter, have a lath or needle shape, or be curved; they may be found intermingled with other platy particles (fig. 1). So far, the ranges for diameter, length, and aspect ratio are 0.1-2 μm , 1-70 μm , and 3-100 μm respectively. A fairly high proportion (62%) of fibres has been found longer than 5 μm . Comparison of electron and optical microscope counts shows that about a third of the total airborne fibres are detected by the optical technique used for measuring exposure to asbestos at the work place.¹⁸

Dr. McDonald reiterated in a later article that “[t]he Montana deposit was heavily contaminated by asbestiform fibre in the tremolite series.”¹⁹

The scientific consensus that Libby amphiboles are predominantly fibrous and asbestiform in nature was reflected in the Preamble to the 1992 OSHA Asbestos Standard, which contains the OSHA conclusion that the Libby amphiboles are mostly asbestiform:

[Libby] [v]ermiculite, a mica-like ore, was contaminated with four to six percent tremolite-actinolite fibers. Mineralogic analysis of the Libby mine's ore *showed the fibers to be mostly an asbestiform type of fiber*. However, there were also massive amphibole crystals, which when pulverized produced cleavage fragments resembling fibers ... Although the fiber analyses indicate that some of the particles were non-asbestiform in origin, *the predominant fiber exposure appears to be from asbestiform tremolite ...*²⁰

Dr. Lee attempts to turn these findings on their head by claiming that the Libby amphibole is really 90% non-asbestos.

More recently, a Blue Ribbon panel of more than 100 technical and policy experts and other key stakeholders from government, academia, and the private sector evaluated

¹⁸ Attachment 9, J. C. McDonald, et al., Cohort study of mortality of vermiculite miners exposed to tremolite, British J. of Ind. Med., at 439 (1986) (emphasis added).

¹⁹ Attachment 10, J. C. McDonald, et al., Health of vermiculite workers exposed to trace amounts of fibrous tremolite, British J. of Ind. Med. at 630 (1988).

²⁰ Attachment 3, 1992 OSHA Asbestos Standard, § V – Health Effects (emphasis added).

the use and management of asbestos. In its April 2003 report, entitled Asbestos Strategies, Lessons Learned About Management and the Use of Asbestos, the panel noted:

In recent years, much attention has focused on the vermiculite-mining district near Libby, Montana. Concern has also been expressed about exposures to users of products consisting of vermiculite from this location. The Libby vermiculite deposits have been reported to be significantly contaminated with asbestosiform amphiboles ...²¹

Only Dr. Lee believes otherwise.

C. W.R. Grace investigated and concluded that Libby amphiboles are fibrous and asbestosiform in nature.

W.R. Grace conducted extensive studies of the amphibole asbestos contamination of its Libby vermiculite and concluded that the tremolite from Libby vermiculite is fibrous and asbestosiform in nature. For example, in an April 24, 1979 draft response to an inquiry from the Consumer Products Safety Commission, Grace noted that the "Tremolite present in finished products made from Libby vermiculite concentrate is fibrous ..."²² Moreover, Grace discussed internally the airborne exposures from Libby vermiculite asbestos fibers. In a May 24, 1977 memorandum, Elwood Wood, General Manager of Grace's Consumer Products Division, stated, "The exposure problems we have seen to date are limited to the fibrous type of tremolite that occurs in the Libby ore."²³ In a May 12, 1983 letter to the R.T. Vanderbilt Company, Henry Eschenbach, the head of Grace's Health, Safety, and Toxicology Department, wrote:

²¹ Attachment 11 at 16.

²² Attachment 12 at 1.

²³ Attachment 13 at 3.

Attached is a copy of our 8(e) submission to the EPA on the health effects of asbestosiform tremolite in our Libby, Montana operation. As I indicated to you on the phone, the *tremolite causing our problem is clearly an asbestosiform material* which, when examined using phase contrast microscopy, looks somewhat like classical crocidolite or amosite. It is in *no way similar to the blocky inferior stuff* which you people persist in passing off as tremolite.²⁴

Yet, Dr. Lee now claims that Libby tremolite is a 90% blocky, non-asbestos population.

Dr. Lee's revisionist views ignore the fact that Grace had an expert microscopist, Dr. Julie Yang, who was at Johns-Manville before heading up Grace's laboratory. She was very familiar with what asbestos looked like. In a September 16, 1983 report entitled Chemistry of Vermiculite and Asbestos, Dr. Yang provided photographs of asbestos and non-asbestos tremolite.²⁵ The non-asbestos tremolite has a very blocky appearance, whereas the asbestosiform tremolite looks like the fibers observed in the air samples collected in all of the ZAI studies. In her deposition in the EPA Libby Superfund Litigation, Dr. Yang, who had studied Libby for decades, reiterated that the Libby product contains mostly fibrous tremolite:

- Q. Dr. Yang, are there generally fibrous and nonfibrous tremolite fiber in materials that we have just discussed: that is, expanded material concentrate?
- A. In all Grace product or in vermiculite product or in what?
- Q. Let's take them one at a time, if we might. Ore concentrate coming from Libby, are there fibrous and nonfibrous tremolite?
- A. Mostly fibrous material. Fibrous tremolite in Libby product.²⁶

²⁴ Attachment 14 (emphasis added).

²⁵ Attachment 15.

²⁶ Attachment 16, Deposition of Julie Yang in U.S. v. W.R. Grace & Co. at 63: 3-17 (Aug. 21, 2002).

D. Dr. Lee's opinion contradicts the findings of his own laboratory.

1. Dr. Lee's laboratory found predominantly asbestiform tremolite in ZAI.

The R.J. Lee Group collected five bulk samples of ZAI from the home in New York.²⁷ The laboratory separated each sample into sub-samples, representing the top, middle, and bottom of the ZAI, as found in the attic.²⁸ In addition, the laboratory separated each sub-sample into two particle sizes, greater than 500 microns and less than 500 microns.²⁹ The purpose of the separation was presumably Dr. Lee's view that the smaller particles are more likely to contain respirable fibers that can become airborne.³⁰ Dr. Lee's laboratory then analyzed the samples using PLM as outlined in EPA/600/R-93/116, Method for the Determination of Asbestos in Bulk Building Material.³¹

The laboratory determined the amount of asbestiform and non-asbestiform amphiboles in each of the samples, finding that the amount of asbestiform tremolite in the sub-sample consisting of particles that were 500 microns or greater in size ranged from 0.5% to 2.63%.³² In the "500 microns or greater" sub-sample, Dr. Lee generally found a greater amount of asbestiform tremolite.³³ For example, in the sample which was found

²⁷ Attachment 17, R. J. Lee Group Project Report at 4.

²⁸ Id.

²⁹ Id.

³⁰ Attachment 4, Lee Deposition at 76:5-22, 79:2-7; see also Attachment 2, Lee Report at 25. Claimants disagree with Dr. Lee's conclusion. Asbestos bundles greater than 500 microns in size are highly friable and capable of breaking up into respirable sized fibers when disturbed.

³¹ See Attachment 17 at 1.

³² Attachment 17 at 4.

³³ Attachment 4, Lee Deposition at 74:18-21.

to contain a total of 2.63% asbestiform tremolite in the larger particles, the amount of asbestiform versus non-asbestiform tremolite was as follows:³⁴

	Asbestiform tremolite	Non-asbestiform tremolite
Top layer	1.4%	0.1%
Middle layer	2.9%	1.8%
Bottom layer	3.4%	3.2%

This chart shows that there was more asbestiform tremolite than non-asbestiform tremolite in each layer. Yet Dr. Lee now claims that 90% of the tremolite as a whole is non-asbestiform. This makes no sense.

Dr. Lee's laboratory also analyzed the other sub-sample of fine dust that was less than 500 microns in size, using a point counting technique. This technique allows the analyst to calculate the percentage of asbestiform and non-asbestiform particles. The form used to document the analysis has blocks for reporting asbestiform and non-asbestiform fibers.³⁵ For these samples, Dr. Lee's laboratory found between 0.36 and 0.85% asbestiform tremolite/actinolite. Dr. Lee's laboratory reported *no* non-asbestiform tremolite in any of these samples.³⁶ The samples were each noted to be homogenous, and the only other particles noted were vermiculite opaques.³⁷ Yet Dr. Lee now claims 90% of the particles from ZAI are non-asbestiform.

Dr. Lee's own analysis demonstrated that there was a fibrous asbestiform population of amphiboles in the fine dust: (1) the samples of ZAI contained as much as 2.59% amphiboles; (2) the coarse material contained a greater percentage of asbestiform

³⁴ Attachment 17 at 4.

³⁵ Attachment 17.

³⁶ Attachment 4, Lee Deposition at 94: 1-21.

³⁷ Id. at 92: 1-12.

than non-asbestiform amphiboles; and (3) the fine material contained only asbestiform amphibole fibers. Dr. Lee's subsequent opinion, based on his unsupported protocol, that over 90% of the particles counted in Grace's ZAI study (and every other ZAI study) are non-asbestiform cleavage fragments is clearly unsupported and contrary to the facts.

2. Even using extreme measures, Dr. Lee's laboratory could not produce large numbers of non-asbestiform cleavage fragments from Libby tremolite.

Dr. Lee's current opinion is inconsistent with the known propensity of asbestiform tremolite to fragment into fibers and become airborne, while non-asbestiform tremolite will not do so readily. Libby amphibole asbestos bundles are highly friable and readily separable into fibers. Libby's non-asbestiform rock does not break down readily. In fact, Dr. Lee's laboratory could not break it down into respirable particles by hitting it with a hammer and concluded that it could not become airborne.³⁸

This difference in ability to aerosolize was known to Grace. Grace consistently observed that the asbestiform amphiboles were highly friable and likely to break up into respirable particles. For example, in an April 8, 1976 internal Grace report, entitled Characterization and Preparation of Respirable Sized Tremolite Fiber and Vermiculite for Animal Studies, Dr. Yang noted that "the Tremolite bundles are ... soft, and sometimes waxy in touch. They broke down easily to fine fibrils when degraded ..." ³⁹ In her report, Dr. Yang observed the difference between the tremolite rock and the soft tremolite bundles, and noted that the fibers "are quite different than the tremolite found in

³⁸ Attachment 2, Lee Report at 27.

³⁹ Attachment 18 at 2.

associated veins in rock form; they are generally harder and harsher, most of which were removed in the floatation process.”⁴⁰

In an October 4, 1976 memorandum, Grace’s Vice President of Manufacturing and Engineering, J.W. Wolter, discussed options for removing the Libby amphiboles and described the two types:

We felt that tremolite is basically of two types – one that is relatively rocky and does not fragment or does not show a high degree of friability and this material we would probably have to separate through a series of roll screenings. We also notice that some tremolite is both fibrous and very friable and likely to break down.⁴¹

Just as Grace knew two decades earlier, Dr. Lee concluded that ZAI contained both fibrous and non-fibrous tremolite. His laboratory calculated the fibrous tremolite to be approximately 50% of the total tremolite in the ZAI. He also separately concluded that the remaining non-fibrous tremolite could not be broken down into particles resembling fibers even when he smashed the tremolite with a hammer. Thus, the non-fibrous tremolite could not release fiber-like particles into the air.

Nevertheless, Dr. Lee now claims that when the ZAI was disturbed during the attic testing, the fibrous tremolite somehow “stayed put,” while the non-fibrous tremolite, (which Dr. Lee contends cannot be fragmented even with a hammer), somehow launched 90% of the airborne particles. But there is no physical explanation why the fibrous tremolite would resist becoming airborne, while the non-fibrous tremolite could launch enormous numbers of “cleavage fragments” into the air with minimal disturbance of the ZAI.

⁴⁰ Id.

⁴¹ Attachment 19.

Dr. Lee's microscopic manipulation simply does not "fit" with any other Libby vermiculite measurements over the past fifty years (including those by Grace, EPA, and other Grace experts). Nor does it fit with Dr. Lee's own bulk sampling data. Simply stated, a product that is more than half fibrous tremolite cannot launch 90% non-fibrous particles into the air. At a bare minimum, and assuming that fibrous and non-fibrous tremolite became aerosolized at the same rate (which does not happen because the fibrous tremolite aerosolizes much more easily), at least 50% of the tremolite in the air would be fibrous tremolite. Dr. Lee's "disappearing act" for the fibrous tremolite defies logic. For this reason alone, Dr. Lee's opinions regarding cleavage fragments should be excluded.

E. Dr. Lee's "cleavage fragments" do not fit the diameter of cleavage fragments in the published scientific literature.

Dr. Lee agreed in his deposition that the vast majority of cleavage fragments found in nature are greater than one micron in diameter.⁴² This is supported by OSHA, which specifically states, "Most cleavage fragments of the asbestos minerals are easily distinguishable from the asbestos fibers. This is because true cleavage fragments usually have larger diameters than 1 micron."⁴³ As discussed in the affidavit of Dr. Longo, the fibers that Dr. Lee categorizes as cleavage fragments are predominantly one micron or less in diameter. In fact, 69% of the fibers that Dr. Lee calls "cleavage fragments" are one micron or less in diameter.⁴⁴ Eighty percent of all particles counted by the R.J. Lee

⁴² Attachment 4, Lee Deposition at 216:12-20.

⁴³ Attachment 20, OSHA Polarized Light Microscopy of Asbestos, Method ID-191 at 9 (1992).

⁴⁴ Attachment 21, William Longo Affidavit at Par. 10 ("Longo Affidavit").

Group are one micron or less in diameter. For all fibers counted by MAS, 92% are one micron or less in diameter.⁴⁵ Once again, this clearly contradicts Dr. Lee's findings.

F. Dr. Lee's "cleavage fragments" do not fit the aspect ratio of cleavage fragments in the published scientific literature.

Dr. Lee has agreed with the scientific consensus that "[p]opulations of cleavage fragments and populations of asbestos fibers can be distinguished from one another when viewed as a whole, because cleavage fragments are likely to be thicker and shorter than asbestos particles, and will therefore have lower aspect ratios."⁴⁶ The aspect ratio of a fiber is its length to width ratio. Longer and thinner fibers have higher aspect ratios. Cleavage fragments are usually "blocky" (shorter and thicker). As discussed below, the published, peer-reviewed, scientific literature demonstrates that cleavage fragments generally have an aspect ratio of less than 10 to 1. As stated in Dr. Longo's affidavit and acknowledged by Dr. Lee, the fibers that Dr. Lee excluded as "cleavage fragments" have an average aspect ratio exceeding 20 to 1. This is much higher than the minimum fiber aspect ratios designated by OSHA (3 to 1) and EPA (5 to 1), i.e., the fibers Dr. Lee excluded as cleavage fragments are much thinner and longer than cleavage fragments would be. The excluded particles are in the classic fiber range.

While the aspect ratio has little mineralogical significance for individual particulates, it is a well-established way to distinguish between asbestosiform and non-asbestosiform populations.⁴⁷ In Dr. Lee's April 2003 publication on the mineralogical

⁴⁵ Attachment 21, Longo Affidavit, Attach. F.

⁴⁶ See Attachment 2, Lee Report at 12.

⁴⁷ See Attachment 22, Campbell, et al., Selected Silicate Minerals and Their Asbestosiform Varieties at 44, Bureau of Mines Information Circular (1977).

differences between asbestos fibers and cleavage fragments, he recognized that long, thin particles describe a fibrous population:

[T]he aspect ratio concept, when used with caution, can be useful in distinguishing the asbestosiform or nonasbestiform nature of a given dust population. Due to the tendency of asbestosiform fiber bundles to separate into thinner and thinner fibers when pressure is applied (i.e., ground), the aspect ratio tends to remain high. In contrast, because nonasbestiform minerals break or cleave in a more random fashion, few relatively long, thin particles are produced. Nonasbestiform dust populations will, therefore, generally retain low aspect ratio characteristics.⁴⁸

The scientific consensus is that to the extent particles can cleave from non-asbestiform tremolite rock and take the shape of elongated fragments, they generally have aspect ratios of less than 10 to 1. For tremolite-actinolite asbestos, EPA states that "cleavage fragments may be present with aspect ratios < 10 to 1."⁴⁹ Dr. Ilgren, another Grace expert, agreed that cleavage fragments do not have average aspect ratios as high as 20:1 (as Dr. Lee contends):

Q. Let's talk about aspect ratios. Again, I know it's hard to put an average on this, but just tell me generally if you could what you would expect to find in terms of an aspect ratio for cleavage fragments.

A. I think they're largely less than 20:1, probably more in the 10:1.

Q. Would you say that you would find more cleavage fragments with an aspect ratio less than 10 to 1 than you would greater than 10 to 1?

A: I would think so, sure. Just by nature of their mode of growth, it would stand to reason. ...⁵⁰

⁴⁸ Attachment 8, R.J. Lee, et al., Asbestiform and Nonasbestiform Mineral Growth Habit and Their Relationship to Cancer Studies at 12 (Apr. 2003).

⁴⁹ Attachment 23, R.L. Perkins, et al., Method for the Determination of Asbestos in Bulk Building Materials, EPA/600/R-93/116 at 2, 19, table 2-2 (July 1993).

⁵⁰ Attachment 24, Deposition of Edward Ilgren at 127:12-23 (May 22, 2003).

Dr. Ilgren's view that cleavage fragments most often have a 10 to 1 aspect ratio or less is directly contrary to Dr. Lee's assertion that the particles he counted with a 20 to 1 aspect ratio are cleavage fragments.

Other researchers have published their findings that tremolite cleavage fragments are typically very short and blocky. Campbell evaluated milled tremolite and found that 70% of the tremolite cleavage fragments had an aspect ratio of less than 3 to 1, and 95% of the tremolite cleavage fragments had an aspect ratio of less than 10 to 1.⁵¹ He included photomicrographs that graphically depict the difference between asbestos and non-asbestos tremolite. The particles that Dr. Lee identifies as ZAI cleavage fragments look very much like the asbestos tremolite and very little like the cleavage fragments in Campbell's study.⁵²

In an article published by the National Bureau of Standards in 1980, Dr. Lee himself proposed a working definition for asbestos using the electron microscope to eliminate non-asbestos particles.⁵³ Dr. Lee's proposal incorporated a minimum aspect ratio of 10 to 1 to eliminate most cleavage fragments:

For a routine method, a minimum aspect ratio of 10:1 should be used in a screening analysis or survey. Existing data indicate that this would not affect the chrysotile analysis at all and amphibole analysis only when the sample contains a significant percentage of acicular nonasbestos particles ... While this would undoubtedly result in missing 5 to 20 percent of the short asbestos particles, it would eliminate 70 to 80 percent of the nonasbestos particles from consideration.⁵⁴

⁵¹ Attachment 25, Campbell, et al., Relationship of Mineral Habit to Size Characteristics for Tremolite Cleavage Fragments and Fibers, Bureau of Mines Report of Investigations 8367 at 13 (1979).

⁵² See id. (displaying photomicrographs throughout article which depict asbestos and non-asbestos particles).

⁵³ Attachment 26, R. J. Lee, et al., Considerations in the Analysis and Definition of Asbestos Using Electron Microscopy, National Bureau of Standards Special Publication 619 (Mar. 1982).

⁵⁴ Id. at 136.

In contrast to Dr. Lee's published work saying that a 10:1 aspect ratio would eliminate 70-80% of the non-asbestos particles, he now claims that most non-asbestos particles are much longer, with a 20:1 average aspect ratio.

Grace investigated the cleavage fragments associated with its Libby vermiculite and also concluded that the cleavage fragments generally had an aspect ratio of less than 10 to 1. In a May 24, 1984 letter to OSHA, Grace noted that "[t]he Libby ore body contains tremolite asbestos as well as non-asbestiform tremolite as contaminants."⁵⁵ Grace recognized that the non-asbestiform amphiboles can exist as "crystalline or blocky mineral forms" and noted:

It is not uncommon for some of these blocks or chunks to appear in a microscope as particles with an aspect ratio of 3 to 1. However, they are clearly not fibrous. Clarifying the definition would exclude these materials from fiber counts and make monitoring results more precise.⁵⁶

Grace proposed raising the aspect ratio to 5:1 or 10:1, to eliminate cleavage fragments from being counted. Grace stated:

Grace also supports a change in the aspect ratio to at least 5 to 1 and preferably 10 to 1. Frequently, particles having a 3 to 1 ratio are clearly not fibrous, but must be counted to technically comply with the present standard. We believe instituting a higher ratio will also increase the precision of real-fiber counting.⁵⁷

Yet Dr. Lee now claims that particles Grace told OSHA would be "real fibers" at a 10:1 aspect ratio are actually cleavage fragments.

⁵⁵ Attachment 27 at 1.

⁵⁶ Id. at 2.

⁵⁷ Id.

Dr. Ann Wylie also proposed raising the aspect ratio from 3:1 to 10:1 as a means of discriminating between asbestos fibers and non-asbestiform cleavage fragments:

Dr. Wylie stated that for particles which are greater than 5 microns in length, the majority of non-asbestiform particles have aspect ratios less than 10:1 and the majority of asbestos particles (i.e. fibers) have aspect ratios greater than 10:1. Thus she concluded that changing the aspect ratio from 3:1 to 10:1 provides a means of excluding non-asbestiform particles from particle counts while maintaining the same asbestos particle counts one would have obtained using the 3:1 aspect ratio.⁵⁸

As set forth in the affidavit of Dr. Longo, the average aspect ratio for all particles, counted by *both* the R. J. Lee Group and MAS in the ZAI studies, is 24 to 1.⁵⁹ Additionally, the average aspect ratio for all fibers which Dr. Lee claims to be "cleavage fragments" is 22 to 1.⁶⁰ Further, approximately 84% of all fibers counted by the R. J. Lee Group have an aspect ratio of 10 to 1 or greater.⁶¹ Seventy-three percent of all particles that Dr. Lee identified as "cleavage fragments" have an aspect ratio of 10 to 1 or greater.⁶² For the MAS data, approximately 85% of all fibers have an aspect ratio of 10 to 1 or greater.⁶³ All these findings are clearly consistent with an asbestiform population of fibers and totally inconsistent with Dr. Lee's opinion that over 90% of the particles are cleavage fragments.

Dr. Lee states that the non-asbestiform cleavage rock is: (1) similar to non-asbestiform amphiboles found in Shiness, Scotland; and (2) different from asbestiform

⁵⁸ Attachment 3, 1992 OSHA Asbestos Standard, §VI - Other Regulatory Issues at 6 (1992).

⁵⁹ Attachment 21, Longo Affidavit at 10, 21.

⁶⁰ Id. at 10.

⁶¹ Id.

⁶² Id.

⁶³ Id. at 21.

tremolite found in Jamestown, California.⁶⁴ The Shiness material has never been shown to have any biological effects, while the Jamestown material has repeatedly been shown to be highly potent.⁶⁵ In his National Stone Association publication, Dr. Lee describes the characteristics of the non-asbestiform tremolite from Shiness and the asbestiform tremolite from Jamestown.⁶⁶ Dr. Lee noted that “the Shiness tremolite dust was almost exclusively composed of cleavage fragments, only a small portion of which had an aspect ratio greater than 3:1.”⁶⁷ On the other hand, the Jamestown asbestiform tremolite had aspect ratios almost identical to those measured by the R. J. Lee Group and MAS. For the Jamestown asbestiform tremolite, 82% of the fibers had an aspect ratio of greater than 10 to 1.⁶⁸ This is compelling proof that the population of airborne fibers from ZAI is asbestiform in nature and demonstrates that Dr. Lee’s opinions are scientifically unsupportable.

G. EPA has rejected Dr. Lee’s opinions regarding cleavage fragments from Libby vermiculite.

As previously noted, Dr. Lee first conjured up his “cleavage fragment” defense when he was retained by Grace as an expert in the EPA Libby Superfund case. In that case, Dr. Lee opined that 74% of fibers counted by another NVLAP (National Voluntary Laboratory Accrediting Program) certified laboratory were harmless cleavage

⁶⁴ Attachment 2, Lee Report at 29.

⁶⁵ Id.

⁶⁶ Attachment 8, Asbestiform and Nonasbestiform Mineral Growth Habit and Their Relationship to Cancer Studies at 25 (Apr. 2003).

⁶⁷ Id. at 52.

⁶⁸ Id. at 25. As discussed above, the R. J. Lee Group found 84% of all fibers counted had an aspect ratio greater than 10 to 1, and MAS found that 85% had an aspect ratio greater than 10 to 1.

fragments.⁶⁹ An EPA toxicologist, Dr. Weis, evaluated Dr. Lee's opinions regarding cleavage fragments and concluded, "in short, R.J. Lee misrepresents the findings of peer reviewed papers that he used to reference his position, and this misrepresentation undermines the validity of his conclusions."⁷⁰ In its response to Grace's position papers, EPA rejected Dr. Lee's opinions regarding cleavage fragments:

Dr. Lee's statements about the inappropriate counting of cleavage fragments do not have merit. EPA has counted asbestiform fibers and structures pursuant to the counting criteria of the methods being implemented. The counting criteria dictate discerning fibers by length, width, aspect ratio and specific physical characteristics. Following these rules, the EPA laboratories have consistently reported to EPA that the fibers found in air samples collected are populated almost exclusively with Libby amphibole fiber. (See Reservoirs and EMSL memorandums on this issue in the Administrative Record.) EPA, USGS and several other researchers (including researchers for W.R. Grace) have evaluated the nature of the mineral habit of the Libby amphibole asbestos in the Libby vermiculite. *With the exception of Dr. Lee, these researchers have all concluded that the amphibole population is fibrous in nature. They all also agree that the amphibole asbestos in Libby vermiculite is quite friable, giving off airborne fibers when disturbed.* Such research has been performed by Dr. Julie Yang of W.R. Grace, Greg Meeker of USGS, Arthur Langer, Dr.'s McDonald and Sebastien at McGill University, Dr. Amandus at NIOSH, Dr. Wake of the State of Montana, and others. Also, EPA has found that the size and shape of fibers seen today, whatever their make-up, are similar to those to which workers were exposed to in Libby in the past (see discussion in Section D below). These fibers clearly have been associated with asbestos-related disease in Libby and there is no basis for excluding them from exposure estimates. *In fact, Dr. Lee's assertion that EPA has included a large number of cleavage fragments in its exposure estimates is without any factual foundation.* While Dr. Lee discusses a few studies on the toxicological effects of fibers of different length and width, he offers no concrete criteria on how he defined a cleavage fragment. His determination is contrary to the information which has been presented to EPA and to the regulatory and methodological frameworks established for asbestos assessment.⁷¹

⁶⁹ Attachment 28, Lee Report in U.S. v. W. R. Grace & Co., at 86 (July 29, 2002).

⁷⁰ Attachment 29.

⁷¹ Attachment 30 at 13 (emphasis added).

In the EPA Libby Superfund litigation, the District Court ignored Grace's arguments based on Lee's opinions and granted the EPA summary judgment on the reasonableness of EPA's response actions.⁷²

H. The results from Dr. Lee's laboratory are unreliable.

Dr. Lee's willingness to make whatever "laboratory findings" Grace needs is representative of a broader problem of scientific unreliability. On April 9-10, 2001, the federal government conducted an on-site investigative audit of Dr. Lee's laboratory in California.⁷³ The report noted:

The primary purpose of this non-routine audit was to investigate discrepancies between the PLM results reported by the R. J. Lee Group, Inc. and those reported by the quality control laboratory, Forensic Analytical. Two sets of pulverized rock samples were received by the R.J. Lee Group, Inc. from the Department of Toxic Substances Control (DTSC) and later forwarded to Forensic Analytical. Both laboratories prepared and analyzed the samples in accordance with the California Air Resources Board (CARB) Method 435. However, the results reported by the two laboratories for several samples showed significant variance, including some that differed by nearly a factor of twenty (20) ... The complete training records for the laboratory personnel involved in the handling, preparation, analyses, and reporting of possible ACMs were not available to the auditors during the laboratory investigation. The training records for all employees and all QA/AC records are maintained by the QAO at the corporate office, and although partial training and QC/QC [sic] records were submitted to the auditors by facsimile upon request, the records were incomplete. The requirement that training records for employees be maintained at the facility in which they work is described in Section 4.1 of the PLM QAPP. Also, Section VII of SOP 31 states, "all records kept by the QA unit shall be kept in one location at the laboratory. Laboratory management stated to the audit team that all microscopists are required to have a formal/advanced education in a related field. However, no such training records were provided to the audit team confirming the analysts' credentials.⁷⁴

⁷² Attachment 31, Order in U.S. v. W. R. Grace & Co. (Dec. 19, 2002).

⁷³ Attachment 32, EPA, Summary On-Site Audit Report, R. J. Lee Group, Inc. (May 1, 2001).

⁷⁴ Id. at 1-3.

The auditors concluded that “[t]he overall evaluation of the laboratory revealed procedural weaknesses with regard to a lack of on-site QA/QC program, compliance with laboratory SOPs and methodology, sample handling, record keeping, and incomplete documentation of analytical results.”⁷⁵

Most recently, EPA has issued a notice to all EPA regions urging caution when using the R.J. Lee Group as a result of the discrepancies discussed in the audit.⁷⁶ EPA stated:

The purpose of this memorandum is to encourage Superfund regional project managers to thoroughly review any site management decision for asbestos contaminated sites where analytical data generated by asbestos testing laboratories associated with RJ Lee Group, Inc. were critical ... Issues documented in the onsite audit include, but are not limited to the following:

- Lack of appropriate laboratory specific Standard Operating Procedures (SOP) describing precise laboratory procedures, especially for operations that may be modifications or deviations from published methodology ...
- Failure to adequately perform method-required Quality Assurance (QA) analyses. Methods require laboratories to analyze sample duplicates and QA reference slides at specified frequencies. The laboratory failed to perform QA analysis at the frequencies detailed by the methods. The laboratory was cited for this failure during a 1999 internal QA audit, but has failed to provide appropriate corrective action ...
- Lack of supervisory review of analytical data.
- Lack of documentation supporting credentials and training of analysts.
- Inconsistencies in client reports in which reported results do not match raw data ...

⁷⁵ Id. at 8.

⁷⁶ See Attachment 33, EPA Memorandum from Michael B. Cook to Superfund Regional Managers (June 19, 2003).

Further, there is concern that questionable practices observed at the San Leandro facility may also reflect the procedures used at other RJ Lee Group testing laboratories throughout the United States. Therefore, OERR is recommending that Regions review data for all RJ Lee Group testing facilities that may have been involved in testing of asbestos samples, including samples of vermiculite products or raw ore which may have come from Libby, Montana, and may be contaminated with asbestos.⁷⁷

A prime example of such “questionable practices” is Dr. Lee’s manipulation of scientific techniques to try to “spin” asbestos fibers into cleavage fragments. This may be an effort worthy of a fairy tale, but not the courtroom. This testimony should be excluded.

IV. CONCLUSION

Dr. Lee’s testimony concerning cleavage fragments should be excluded because it is unscientific and unreliable. Dr. Lee utilized an unpublished, unauthorized analytical protocol in an attempt to minimize fiber counts. All of the fibers excluded by Dr. Lee meet the dimensional criteria of asbestos. The consensus in the scientific community is that Libby amphiboles are fibrous and asbestos in nature. Dr. Lee’s opinions contradict Grace’s own conclusions and the findings of Dr. Lee’s laboratory. Further, Dr. Lee’s opinions do not fit the established width and aspect ratio criteria for cleavage fragments in the scientific published literature. EPA, which has extensively studied the asbestos problems resulting from Libby vermiculite, has reviewed and rejected Dr. Lee’s opinions regarding cleavage fragments as being “without any factual foundation.” Finally, a recent government audit has found Dr. Lee’s laboratory to engage in questionable practices.

Because Dr. Lee’s opinions are unsupported by the facts of this case and the consensus of the scientific community, his opinions do not meet the requirements of

⁷⁷ Id. at 1-2 (emphasis added).

Daubert and Rule 702. For these reasons, Dr. Lee's opinions regarding cleavage fragments are inadmissible as a matter of law.

RESPECTFULLY SUBMITTED,



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